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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,510	06/02/2000	Harry Leneau	503775.008	7522

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Penny R Slicer
Stinson Mag & Fizzell PC
1201 Walnut
Suite 2800
Kansas City, MO 64106

EXAMINER

SCHWADRON, RONALD B

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 04/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/586,510

Applicant(s)
Leneau et al.

Examiner
Ron Schwadron

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 14, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

1. Applicant's election of the species intratracheal injection and IgG in Paper no. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse. See MPEP section § 818.03(a)).
2. Claims 1-20 are under consideration. A search of the prior art has indicated that all of the species recited in the claims are free of the prior art and therefore all of the claims have been examined.
3. Applicants need to update the status of US application 08/685052 disclosed in page 1 of the specification (eg. now abandoned).
4. Regarding the IDS filed 6/2/2000, the Erickson reference was not considered because it was supplied in incomplete form (the bottom part of the pages was missing from the supplied copy) and the Baker et al. reference was not considered because it was supplied in incomplete form (parts of the sentences in the left column were not copied and parts of the bottom of the pages were not copied).
5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "stress induced respiratory disorder" because it is unclear what this means or encompasses. Said phrase is not defined in the

specification and it has no art recognized definition. It is unclear as to what diseases would be encompassed by the term "stress induced respiratory disorder".

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the claimed method of treating exercise induced pulmonary hemorrhage (EIPH) or "stress induced respiratory disorders per se" to the extent that said phrase encompasses EIPH or EIPH like disorders. The specification does not disclose how to use the instant invention for treating EIPH in vivo. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification. Judge Lourie stated in Enzo Biochem Inc. v. Calgene Inc. CAFC 52 USPQ2d 1129 that:

The statutory basis for the enablement requirement is found in Section 112, Para. 1, which provides in relevant part that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

35 U.S.C. Section 112, Para. 1 (1994). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention

without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S* , 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright* , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.* , 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), which in this case is October 20, 1983 for both the '931 and '149 patents.

We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., *Wands* , 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands* , we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.* , 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

The state of the art is such that is unpredictable in the absence of any evidence as to how the instant invention could be used for the treatment of EIPH. As per *Wands* factor (3), the specification provides no working examples indicating that the method of the instant invention can be used for the treatment of EIPH. Erickson et al. teach that while the cause of EIPH is unclear, it appears to involve stress failure of pulmonary capillaries(see pages

53 and 54). There is no evidence of record to suggest that IgG administration would have any effect on stress failure of pulmonary capillaries. Thus, it would be unpredictable as to whether IgG could be used to treat EIPH because there is no evidence of record to establish that IgG has any effect on stress failure of pulmonary capillaries. Thus, as per Wands factors (5) and (7), there is a high degree of unpredictability in the art and the prior art does not disclose evidence indicating that IgG can be used to treat EIPH. Furthermore, to the extent that the claims encompass Ig administration other than IgG, Hillidge et al. teach that IgE levels are actually increased in horses suffering from EIPH (see abstract). Undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification and the prior art alone. See Ex parte Forman, 230 USPQ 546, BPAI, 1986.

9. The claimed inventions are not disclosed in parent application 08/349010 and therefore regarding the application of prior art, priority is extended only to parent application 08/685052.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Levinson et al.

Levinson et al. teach treatment of steroid dependent asthma with IVIG (a composition containing immunoglobulins). While it is unclear as to what "stress induced respiratory disorder" means or encompasses for the reasons elucidated above, depending on how "stress induced" is interpreted, the term "stress induced respiratory disorder" could potentially encompass any respiratory disorder.

12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Van Wye et al.

Van Wye et al. teach treatment of pulmonary PA infection in cystic fibrosis patients with hyperimmune globulin (a composition containing immunoglobulins). While it is unclear as to what "stress induced respiratory disorder" means or encompasses for the reasons elucidated above, depending on how "stress induced" is interpreted, the term "stress induced respiratory disorder" could potentially encompass any respiratory disorder.

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hemming et al.

Hemming et al. teach treatment of RSV with hyperimmune globulin (a composition containing immunoglobulins). While it is unclear as to what "stress induced respiratory disorder" means or encompasses for the reasons elucidated above, depending on how "stress induced" is interpreted, the term "stress induced respiratory disorder" could potentially encompass any respiratory disorder.

14. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Ragland et al.

Ragland et al. teach treatment of equine respiratory disease with equine immunoglobulin (a composition containing immunoglobulins). While it is unclear as to what "stress induced respiratory disorder" means or encompasses for the reasons elucidated above, depending on how "stress induced" is interpreted, the term "stress induced respiratory disorder" could potentially encompass any respiratory disorder.

15. No claim is allowed.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

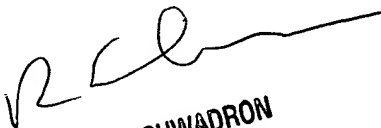
17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan

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can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644



RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1640 1644